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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,816	09/25/2003	Vernon G. Wong	440882000201	6866

7590 01/12/2006

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EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/671,816	Applicant(s) WONG ET AL.	
	Examiner Casey Hagopian	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 35,37-39,42-47,51,52,55,56 and 61-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35,37-39,42-47,51,52,55,56 and 61-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Receipt is acknowledged of applicant's Request for Continued Examination filed 10/12/2005.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Independent claim 35 and its depending claims 37-39, 42-47 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** Claim 35 is drawn to a bioerodible implant for treating an inflammation-mediated condition of an eye in an individual, the implant comprising a steroidal anti-inflammatory agent and a bioerodible copolymer without an added release modifier. The original disclosure filed 9/25/2003 does not include teachings of a bioerodible implant *without an added release modifier*. The claims within this rejection are examined as written by the applicant; at this time new matter must be considered as part of the claimed subject matter.
4. Independent claim 35 and its depending claims 37-39, 42-47 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description

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requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 35 is drawn to a bioerodible implant for treating an inflammation-mediated condition of an eye in an individual, the implant comprising a steroidal anti-inflammatory agent and a bioerodible copolymer without an added release modifier. Paragraph 0052 in the instant specification states that release modulator may be included in the implants and the amount of the release modulator employed is dependent on several factors. Similarly, paragraph 0054 of the instant specification discusses proportions of glucocorticoid, polymer, and modifiers and how they may be determined. Additionally, the examiner found no statements, either positively or negatively, or examples of "an added release modifier". For these reasons, it is the position of the examiner that the original disclosure teaches away from the exclusion of an added release modifier. Thus, it would be difficult for one skilled in the relevant art to make and use the claimed bioerodible implant comprising an added release modifier.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Independent claim 35 and its depending claims 37-39, 42-47 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 35 includes the limitation "without an added release modifier". It is not

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clear what an added release modifier is or what ingredients may be defined as an added release modifier. Thus, the claims are vague and indefinite.

7. Independent claims 35 and 52 and their depending claims 37-39, 42-47, 51, 55-56, and 61-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 35 and 52 include the limitation "with a weight between about 500  $\mu$ g and about 1100  $\mu$ g". It is not clear as the claims are written whether the weight is referring to the filament or the implant. The examiner is assuming that the weight is referring to the implant as there is support in the specification for such a claim, however it is suggested that the claims are amended to clarify if the weight is indeed referring to the filament or the implant.

8. Claims 37-39, 42-46 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of aforementioned claims recites the limitation "The implant..." in the first line of each of the claims. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the claims be amended to read "The bioerodible implant..." in order to have proper antecedent basis.

9. Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation "The method..." in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

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10. Claims 46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation "the inflammation mediated condition" in the second line of the claims. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the claims be amended to read "the inflammation-mediated condition" in order to have proper antecedent basis.

11. Independent claim 52 and its depending claims 55-56, and 61-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation "the agent" in the sixth line of the claim. There is insufficient antecedent basis for this limitation in the claim.

12. Claims 55, 56, and 61-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation "the steroidal anti-inflammatory agent" in the second line of the claims. There is insufficient antecedent basis for this limitation in the claim.

13. Claims 64-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation "the bioerodible polymer" in the second line of the claims. There is insufficient antecedent basis for this limitation in the claim.

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14. Claim 66 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation "the inflammatory mediated condition" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the claim be amended to read "the inflammation-mediated condition" in order to have proper antecedent basis.

### ***Conclusion***

15. All claims have been rejected; no claims are allowed.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on M-F from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

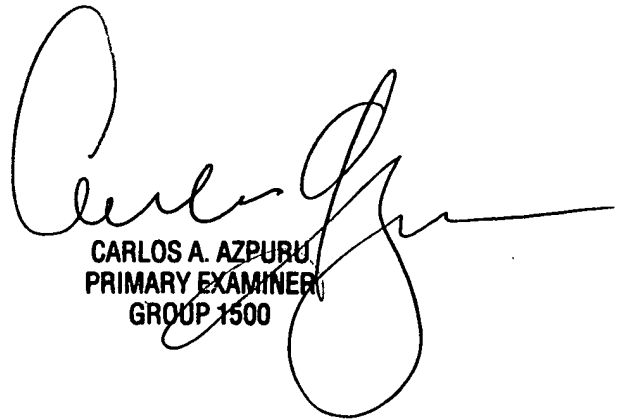
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic  
Business Center (EBC) at 866-217-9197 (toll-free).



Casey Hagopian  
Examiner  
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